

Attorney Docket No.: 9537-3
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This listing of the claims replaces all prior versions in the application.

Listing of Claims:

1. (Currently Amended) An implantable prosthesis of shape generally similar to that of a spinal intervertebral disc ~~devoid of internal reinforcing material and rigid endplates and being a single non-articulating body~~ [[,]] comprised of only a single solid biocompatible elastomer with an ultimate strength in tension greater than about 100 kiloPascals, that exhibits the flexibility to allow at least 10 degrees of rotation between the top and bottom faces with torsions of at least 1 N-m without failing, wherein the single body defines an exposed surface that is modified to provide specific surface characteristics.

2. (Previously Presented) A prosthesis according to Claim 1 wherein the device has a compressive strength sufficient to withstand a compressive load greater than 1 MegaPascals.

3. (Previously Presented) A prosthesis according to Claim 1 wherein the device has an ultimate strength in tension and compression which is greater than 1 MPa.

4. (Previously Presented) A prosthesis according to Claim 1 wherein the device is a molded freeze-thaw body formed of a single solid elastomeric cryogel material formed from a mold formulation of polyvinyl alcohol (PVA) powder in an amount of between 25% to 50% by weight and solvent.

5. (Previously Presented) A prosthesis according to Claim 1 wherein the elastomer has a compressive strength at least 1.0 MPa.

6. (Previously Presented) A prosthesis according to Claim 1 wherein the elastomer has a compressive strength of at least 10 MPa.

7. (Previously Presented) A prosthesis according to Claim 1 wherein the device has a compressive modulus of elasticity that is between 0.1 MPa and 10 MPa.

8. (Withdrawn) A prosthesis according to Claim 1 wherein the elastomer has elasticity that is not constant or that is anisotropic.

9. (Previously Presented) A prosthesis according to Claim 1 wherein the delivered size of the prosthesis can passively expand in at least one dimension over one day, in saline.

10. (Withdrawn) A prosthesis according to Claim 1 wherein the delivered size of the prosthesis can expand at least 5% in at least one dimension over one day, in saline.

11. (Withdrawn) A prosthesis according to Claim 1 wherein the delivered size of the prosthesis can expand at least 20% over one day in at least one dimension *in vivo* and can generate a cranial-caudal force of greater than 1 Newton.

12-13. (Canceled)

14. (Currently Amended) A prosthesis according to Claim [[13]] 1 wherein the surface characteristics are physically or biochemically modified to provide enhanced adhesion to a vertebral body.

15. (Currently Amended) A prosthesis according to Claim [[13]] 1 wherein the surface includes a fabric.

16. (Currently Amended) A prosthesis according to Claim [[13]] 1 wherein the surface includes a mesh.

17. (Currently Amended) A prosthesis according to Claim [[13]] wherein the surface includes a porous structure with undercuts.

18. (Currently Amended) A prosthesis according to Claim 1 [[13]] wherein the surface includes a rough surface greater than 5 nanometers.

19. (Currently Amended) A prosthesis according to Claim 1 [[13]] wherein the surface includes a bioactive molecule.

20. (Previously Presented) A prosthesis according to Claim 1 wherein the top and bottom surfaces have surface characteristics that allow cellular ingrowth.

21. (Previously Presented) A prosthesis according to Claim 1 wherein surface characteristics of the elastomer are biochemically modified to provide enhanced water transport.

22. (Previously Presented) A prosthesis according to Claim 1 wherein surface characteristics of the prosthesis are physically modified to provide enhanced chemical transport.

23. (Currently Amended) A prosthesis according to Claim 1 ~~wherein the device is a unitary non-articulating body, and wherein the body is made of a single solid elastomer, and wherein the exposed surface of the prosthesis includes upper and lower extensions extending above and below the solid elastomer body for fixation to the adjacent vertebral bodies.~~

24. (Currently Amended) A prosthesis according to Claim 1 wherein the prosthesis exposed surface includes a ring of continuous fiber.

25. (Currently Amended) A prosthesis according to Claim [[1]] 24, wherein the ring includes that contains appendages to allow for physical attachment to the vertebral body and to prevent dislodgement *in situ*.

26. (Currently Amended) A prosthesis according to Claim 1 wherein the prosthesis body material is a PVA monolithic cryogel.

27. (Canceled)

28. (Original) A prosthesis according to Claim 1 that is a permanent implantable medical device.

29. (Currently Amended) A sterile prosthesis according to Claim 1 wherein the prosthesis ~~has a body that is an oval or kidney shape for use as a total disc replacement spinal disc prosthesis that substantially corresponds to a shape of a human spinal disc and contacts local vertebrae and is devoid of endplates~~ and allows motion between adjacent vertebrae, has exposed fibers on the cranial and caudal surfaces thereof, and wherein the body is a ~~non-articulating solid monolithic cryogel~~ body having an ultimate compressive and tensile strength greater than 1 MPa, an ultimate tensile stretch greater than 15% in at least one direction, and comprises extensions from the body for attachment to sides of a vertebrae.

30-33. (Canceled)

34. (Currently Amended) An implantable non-articulating total disc replacement spinal disc, ~~having a single non-articulating body with having a superior surface and an inferior surface joined by a circumferential surface, the body defined by only a single solid biocompatible freeze-thaw hydrogel devoid of internal reinforcement material inside the disc body with an ultimate strength in tension greater than about 100 kiloPascals that exhibits the flexibility to allow at least 2 degrees of rotation between the superior and inferior faces with torsions of at least 0.01 N·m without failing, wherein the single body defines an exposed surface that is modified to provide specific surface characteristics.~~

35. (Currently Amended) The implantable spinal disc body of claim 34 wherein the

implantable spinal disc superior and inferior surfaces are substantially that of a kidney corresponding to a human spinal intervertebral disc shape, shaped and formed by an extended oval surface and an indented surface, wherein the cross-section of the implantable spinal disc is substantially rectangular, and wherein the body consists essentially of the solid freeze-thaw hydrogel and fabric mesh, wherein the exposed surface comprises a fabric that is molded to the disc body and extends beyond the body to define fixation appendages.

36. (Original) The implantable spinal disc body of claim 34, wherein the periphery of the superior and inferior surfaces is substantially flat.

37. (Original) The implantable spinal disc body of claim 34, wherein the superior and inferior surfaces have a roughness index of between about 1 nm and about 2 mm in height.

38. (Original) The implantable spinal disc body of claim 37, wherein the circumferential surface has a roughness index of less than 1 mm.

39. (Currently Amended) The implantable spinal disc body of claim 34, wherein the implantable spinal disc body has an external surface that is at least partially surrounded by an attachment extension member having a plurality of superior and inferior tabs connected to a band member for attachment of the implantable spinal disc to adjacent superior and inferior vertebral surfaces, respectively.

40. (Currently Amended) The implantable spinal disc body of claim 34, wherein the superior and inferior surfaces are covered with a surface treatment to promote attachment to adjacent vertebral bodies, and wherein the disc body is devoid of rigid endplates and consists essentially of a monolithic freeze-thaw polyvinyl alcohol (PVA) hydrogel.

41. (Previously Presented) The implantable spinal disc body of claim 34, wherein the superior and inferior surfaces have a plurality of pores to promote tissue ingrowth.

42. (Previously Presented) The implantable spinal disc body of claim 34 wherein an anterior portion of the implantable spinal disc body is of greater thickness than a posterior portion, and wherein the body is configured to have an ultimate strength in tension and compression of at least 1 MPa, and is configured to allow for 10 degrees of rotation with torsions of at least 1 N-m without failing.

43. (Currently Amended) An implantable spinal total disc replacement body consisting essentially of only:

(a) a biocompatible solid polyvinyl alcohol (PVA) cryogel, the body being a single non-articulating body having an ultimate strength in tension greater than about 100 kiloPascals and sufficient elasticity to allow for shock absorption and flexibility of motion between adjacent vertebrae that allows at least 10 degrees of rotation between the top and bottom faces with torsions of at least 1 N-m without failing[,]); and

(b) an attachment extension band member at least partially surrounding an outer circumferential surface of the implantable spinal disc body,

wherein the body is shaped to have:

a substantially concave superior surface having a substantially flat periphery surface; a substantially convex inferior surface having substantially flat periphery; the superior and inferior surfaces being joined by a circumferential surface; and the implantable spinal disc body being further characterized as being of a kidney shape formed by an extended oval surface and an indented portion, having a substantially rectangular cross-section, and having an anterior portion of greater thickness than a posterior portion.

44. (Original) The implantable spinal disc body of claim 43 wherein the superior and inferior surfaces have a roughness index of between about 1 nm and about 2 mm in height and the circumferential surface has a roughness index of less than 1 mm.

45. (Currently Amended) The implantable spinal disc body of claim 43 further comprising[[::]]

~~an attachment extension band member at least partially surrounding an outer circumferential surface of the implantable spinal disc body; and~~

superior and inferior tabs extending from said attachment extension band member for attachment of the implantable spinal disc body to adjacent superior and inferior vertebral surfaces, respectively.

46. (Canceled)

47. (Currently Amended) The implantable spinal disc according to Claim 43, wherein the device has a ~~non-articulating~~ passively expandable ~~monolithic~~ body of freeze-thaw cryogel that defines a core and annulus of the spinal disc implant, and wherein the disc includes fabric moldably attached thereto that extends beyond the body to define fixation appendages.

48. (Currently Amended) An implantable spinal total disc replacement having a single flexible single-piece non-articulating solid body ~~devoid of rigid endplates~~, the body having a nucleus and annulus that are both defined only by a single solid crystalline PVA hydrogel ~~and is devoid of internal reinforcing material~~, the body having a shape generally similar to that of a human spinal intervertebral disc with opposing top and bottom faces, wherein the crystalline PVA hydrogel has an ultimate tensile and compressive strength of at least about 100 kiloPascals and exhibits sufficient flexibility to allow at least 2 degrees of rotation between the top and bottom faces with torsions of at least 0.01 N·m without failing, and wherein the solid body is configured to contact local vertebrae.

49. (Currently Amended) A disc according to Claim 48, further comprising a fabric band attached to an axially extending circumferential exposed surface of the body.

50. (Currently Amended) A disc according to Claim 48, wherein the band is molded to the axially extending outer circumferential surface of the body.

51. (Previously Presented) A disc according to Claim 48, further comprising a porous material attached to superior (top) and inferior (bottom) surfaces of the body to allow for tissue ingrowth from adjacent vertebral tissue *in situ*.

52. (Previously Presented) A disc according to Claim 48, wherein the body is configured to passively axially expand *in situ*.

53. (Withdrawn) A disc according to Claim 48, wherein the body is configured to passively axially expand *in situ* between 5% to 600% over at least about 24 hours.

54. (Withdrawn) A disc according to Claim 48, wherein the body is configured to swell from 5% to six times its original size over 24 hours when placed in a bath of Normal saline.

55. (Withdrawn) A disc according to Claim 48, wherein the body has anisotropic elasticity.

56. (Currently Amended) A disc according to Claim 48, wherein the body is ~~monolithic~~ and has substantially the same durometer for locations proximate the nucleus and the annulus.

57. (Previously Presented) A disc according to Claim 48, further comprising at least one inferior tab and at least one superior tab extending from the body.

58. (Currently Amended) A disc according to Claim 48, wherein the body is configured to passively expand, and wherein the body further comprises fabric moldably

attached to an outer surface thereto with appendages extending outwardly from the body for attaching the disc to sides of target vertebrae.

59. (Currently Amended) A disc according to Claim 48, wherein the disc body has a fabric covering molded to an exposed surface of the disc body to extend beyond the disc body to define fabric appendages used to affix the disc body to target vertebrae.

60. (Previously Presented) A disc according to Claim 48, wherein the body has an ultimate strength in tension and compression of at least 1 MPa to thereby provide a relatively compliant body that has sufficient elasticity to allow flexible motion between vertebrae and act as a mechanical shock absorber.

61. (Previously Presented) A disc according to Claim 60, wherein the body has a mechanical ultimate tensile strength greater than 100 kiloPascals.

62. (Previously Presented) A disc according to Claim 48, wherein the body can withstand 10 degrees of rotation between the top and bottom faces with torsions of greater than 1 N-m.

63. (Currently Amended) A spinal total disc replacement prosthesis having a solid single body consisting essentially of only a freeze-thaw PVA cryogel that defines a core and annulus with mesh fabric moldably attached to only an exposed surface of the solid body to define fixation appendages adapted to attach to local vertebrae, ~~wherein the core is devoid of internal reinforcing material, and wherein the prosthesis is non-articulating and has an ultimate tensile strength that is greater than 100 kiloPascals, and wherein the cryogel body is configured to contact local vertebrae.~~

64. (Currently Amended) A spinal disc prosthesis according to Claim 63, wherein the body is ~~devoid of rigid endplates and exhibits sufficient flexibility to allow at least 10 degrees~~

of rotation between top and bottom faces of the body without failing with torsions of at least 1 N-m.

65. (Previously Presented) A spinal disc prosthesis according to Claim 64, wherein the body has an ultimate stretch in at least one direction of at least 15%.

66. (Previously Presented) A spinal disc prosthesis according to Claim 63, wherein the body is configured to swell from 5% to six times its original size over 24 hours when placed in a bath of Normal saline.

67. (Previously Presented) A spinal disc prosthesis according to Claim 63, wherein the body is configured to passively change size and can withstand at least 2 degrees of rotation between the top and bottom faces with torsions of at least 0.1 N-m without failing.

68. (Previously Presented) A spinal disc prosthesis according to Claim 63, wherein the body has an ultimate tensile stretch greater than 25 % in one direction.

69. (Currently Amended) A spinal disc prosthesis according to Claim 63, further comprising a fabric on a band member attached to a circumferential exposed surface thereof.

70. (Withdrawn) A spinal disc prosthesis according to Claim 63, wherein the body has anisotropic elasticity.

71. (Previously Presented) A spinal disc prosthesis according to Claim 63, further comprising a plurality of axially extending tabs of that are attached to the body and extend beyond upper and lower bounds of the body in the axial direction.

72. (Currently Amended) A spinal disc prosthesis according to Claim 63, further comprising a mesh material disposed on at least one exposed surface of the solid body.

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73. (Currently Amended) A spinal disc prosthesis according to Claim 63, further comprising a fabric molded to an exposed surface of the solid body, wherein, in position, the fabric is affixed to vertebral bone.